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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/870,729	05/30/2001	Anthony P. Shuber	EXT-010CN	9406

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TESTA, HURWITZ & THIBEAULT, LLP
HIGH STREET TOWER
125 HIGH STREET
BOSTON, MA 02110

EXAMINER

TUNG, JOYCE

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 12/02/2002

6

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/870,729

Applicant(s)
Shuber

Examiner
Joyce Tung

Art Unit
1637



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Sep 9, 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16-37 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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Response to Amendment

1. The amendment filed 9/9/2002 has been entered.
2. The rejection of claims 2 and 8-15 under 35 U.S.C. §112, second paragraph is withdrawn.
3. The rejection of claims 1-15 under 35 U.S.C. §112, second paragraph, as being incomplete for omitting essential steps is withdrawn.
4. The rejection of claims 1-4, 7-8, 10-11 and 13-15 under 35 U.S.C. §102 (b) anticipated by Shuldiner et al. is withdrawn.
5. The rejection of claims 5 and 12 under 35 U.S.C. §103(a) over Shuldiner et al. (WO 91/15601) as applied to claims 1-4, 7-8, 10-11 and 13-15 and in view of Mullis et al. (4,965,188) is withdrawn.

NEW GROUNDS OF REJECTION

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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7. Claims 16, 18-19, 21-23, 25, 28-29, 31-34 and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by Shuldiner et al. (WO 91/15601).

Shuldiner et al. disclose a method which can be used to distinguish RNA in the sample from contaminating DNA (See pg. 6, lines 23-27). The method applies a first oligonucleotide primer designated $d_{20}-t_{21}$ which comprises the 3' end, a nucleotide sequence complementary to the 3' end of the RNA and the 5' end, a unique random nucleotide sequence or tag which does not hybridize to the RNA sequence within the sample. The primer is extended (See pg. 7, lines 9-24). In the subsequent steps, primers U_{21} and T_{21} are used in which primer U_{21} comprises the sequence complementary to the single stranded DNA segment produced in step 1 and primer T_{21} comprises the unique nucleotide sequence (See pg. 8, lines 11-28). Primer U_{21} is extended (See pg. 9, lines 1-4) and primer T_{21} is extended in second PCR cycle by hybridizing to the unique 5' sequence (T_{21}) (See pg. 9, lines 6-7). This ^{unique 5' sequence} distinguishes between DNA generated from the RNA-template and possible contaminating DNA (See pg. 7, lines 27-29). The method of Shuldiner et al. leads to logarithmic expansion of the tagged segment of DNA (See pg. 12, lines 26-27).

Applicants argue that Shuldiner et al. address contamination avoidance as opposed to contamination detection. As discussed in the response, the method steps of instant invention are the same as the method steps as discussed in the teachings of Shuldiner et al. above. Although Shuldiner et al. do not verbally disclose or suggest the detection of cross-sample contamination. The method of Shuldiner can be used in the detection of cross-sample contamination since the

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first step of the method of Shuldiner et al. is RNA-specific PCR which can be considered as a previous reaction, then the amplified PCR products is subject to a second step PCR reaction by using a primer which is specific to the unique sequence of original primer (See pg. 7, lines 22-29). The unique sequence of Shuldiner et al. is equivalent to the detection sequence of the instant invention. Since the method of Shuldiner et al. leads to logarithmic expansion of the tagged segment of DNA (equivalent to the amplified detection sequence), one of ordinary skill in the art would have found any detection method available at the time of the instant invention to detect the contamination from previous reaction by using the method of Shuldiner et al..

Applicants further argue that the method of Shuldiner et al. has to be conducted in the same sample. Claimed invention is also can be conducted in the same sample. There is no indication that the sample is conducted in the different samples. Nevertheless, claim 28 describes there are two samples, but there is no phrase that the samples are different.

Thus, the teachings of Shuldiner anticipate the limitations of claims 16, 18-19, 21-23, 25, 28-29, 31-34 and 37.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 24, 26-27 and 35-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shuldiner et al. (WO 91/15601) as applied to claims 16, 18-19, 21-23, 25, 28-29, 31-34 and 37 above, and further in view of Mullis et al. (4,965,188).

The teachings of Shuldiner et al. are set forth in section 8 above and Shuldiner et al. do not disclose the limitations of claims 24, 26-27 and 35-36 that the detection is done with sequence specific nucleic acid probe capture and the samples comprise stool and blood.

Mullis et al. disclose that a process for amplifying any target nucleic acid sequence in a nucleic acid mixture (See the Abstract) and a sequence specific probe capture for detection (See column 5, lines 9-12) and the amplification method of Mullis et al. applies to any sample containing target nucleic acid sequence (See column 42-51).

One of ordinary skill in the art at the time of the instant invention would have been motivate to combine the teachings of Shuldiner et al. and Mullis et al. with a reasonable expectation of success to make the instant invention because Mullis et al. disclose that PCR is

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used to amplify a desired nucleic acid sequence (See the Abstract) and the detection of the nucleic acid sequence is done with a probe (See column 5, lines 8-12). It would have been prima facie obvious to carry out the method as claimed.

Claim Rejections - 35 USC § 112

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 17, 20 and 28-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claim 20 is vague and indefinite because of the language “one primer in said control reaction further comprises an additional sequence 3' to said detection sequence”. It is unclear what is meant by language. Does it mean that the primer comprises an additional sequence at 3' end which is specific for a target in said previous amplification reaction. Clarification is required.

b. Claims 28-37 are vague and indefinite because the language “the amplification of which is desired” is unclear which amplification is referred to.

c. Claims 17 and 30 are vague and indefinite because it is still unclear what is meant by the language “at least one primer in said control reaction is not complementary to any contiguous nucleic acid sequence in said template”.

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12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. Any inquiries concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (703) 305-7112. The examiner can normally be reached on Monday-Friday from 8:00 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (703) 308-1119 on Monday-Friday from 10:00 AM-6:00 PM.

Any inquiries of a general nature or relating to the status of this application should be directed to the Chemical/Matrix receptionist whose telephone number is (703) 308-0196.

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14. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Art Unit 1637 via the PTO Fax Center located in Crystal Mall 1 using (703) 305-3014 or 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Joyce Tung

November 25, 2002


GARY BENZION, Ph.D.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600